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Woodard, Emhardt, Moriarty, McNett & Henry LLP
Suite 3700
Bank One Center/Tower
111 Monument Circle
Indianapolis, IN 46204-5137

EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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05/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/695,068

Applicant(s)

YOUNG ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In light of the ambiguity regarding claims 1, 12-18, 21 and 22 the finality of the previous office action is withdrawn and the following office action is presented.

Furthermore, new grounds of rejection are being presented regarding the term "solid".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 12-18, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Assaker (US Pat. 5,620,444).

Assaker discloses an interconnection apparatus for securing a pair of elongate members, said apparatus comprising a solid shaft (Fig. 15, ref. 25); a first hook (Fig. 15, ref. 29) including a first internal surface having a curved portion (the surface inside the hooked region) configured to at least partly encircle a first one of the pair of non-parallel, elongate members; and a second hook (Fig. 15, ref. 33) including a first end (Fig. 15, ref. 33) unitary to the shaft at a position axially displaced from the first hook, said second hook terminating at a second end (end near ref. 34) spaced laterally from the shaft and comprising a second internal surface (the surface inside the hooked region) having a curved portion (Fig. 17) including a ridge (Fig. 10, ref. 21) extending along said curved portion in a direction from the first end to the second end. The second hook can

be considered to be connected to the shaft at a position axially displaced from the first hook, since it is connected to the shaft at a distance from the first hook, along the longitudinal axis of the shaft.

Assaker discloses an interconnection apparatus for securing a pair of elongate members, said apparatus comprising: a solid shaft (Fig. 15, ref. 25); a first hook (Fig. 15, ref. 29) including a first internal surface (the surface inside the hooked region) having a curved portion (Fig. 15) configured to at least partly encircle a first one of the pair of non-parallel, elongate members; and a second hook (Fig. 15, ref. 33) including a first end (area near ref. 31) unitary to the shaft at a position axially displaced from the first hook, said second hook terminating at a second end (end near ref. 34) spaced laterally from the shaft and comprising a second internal surface (the surface inside the hooked region) wherein the second internal surface curves both in a first direction from the shaft to the second end (Fig. 17) and in a second direction oblique to the first direction (Fig. 10, ref. 21). The internal surface curves in a second direction substantially orthogonal to the first direction. The internal surface curves in a second direction at an acute angle to the first direction. The internal surface curves in a second direction at an obtuse angle to the first direction. One can trace curves over the ridge (Fig. 10, ref. 21) that can be considered to be orthogonal to the first direction, acute to the first direction and obtuse to the first direction.

The apparatus further comprises a first spinal rod (Fig. 17, ref. 42) secured to the first rod connector and a second spinal rod (Fig. 17, ref. 42) secured to the second rod connector, wherein the first spinal rod and the second spinal rod are positioned to lie

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non-parallel to each other. Since the rods are being secured by a hook that does not completely encircle the rods, the rods can still be angled while they are being held in place by the hooks. The first spinal rod and the second spinal rod are positioned to not lie in the same plane. The apparatus of Fig. 15 would cause the rods to lie in different planes, since the hooks are different lengths. The first hook includes a first internal surface that curves both in a first direction and in a second direction oblique to the first direction. The hook curves along the curve of ref. 22 in Fig. 10, curving back towards the shaft, and also curves along ridge 21, across the hook. One can trace a curve across the surface of the ridge that is oblique to the curve of ref. 22 in Fig. 10.

Assaker further discloses an interconnection apparatus for securing an elongate member, said apparatus comprising: a shaft (Fig. 15, ref. 25); a first hook (Fig. 15, ref. 29) including a first end (end near ref. 31) connected to the shaft and terminating at a second end (end at the bottom of the hook) spaced laterally from the shaft, and an internal surface (surface in the hook) configured to engage the elongate member, wherein the internal surface curves continuously both in a first direction from the shaft to the second end (Fig. 15) and in a direction oblique to the first direction (Fig. 10, ref. 21).

The apparatus of Assaker is capable of performing a method of treating a spinal deformity, said method comprising; providing an apparatus according to claim 1; securing a first spinal rod and a second spinal rod to two or more vertebrae; interconnecting the first spinal rod and the second spinal rod by securing the first spinal rod to the first hook and the second spinal rod to the second hook (column 6, lines 25-28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (US Pat. 5,980,523) in view of Assaker (US Pat. 5,620,444).

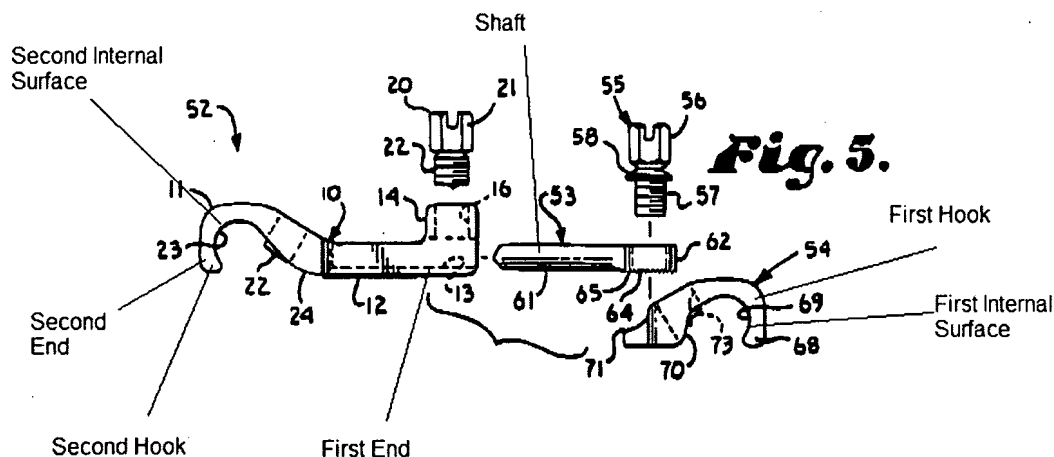
Jackson discloses an interconnection apparatus for securing a pair of elongate members, said apparatus comprising a solid shaft (Fig. 5 below); a first hook (Fig. 5 below) including a first internal surface (Fig. 5 below) having a curved portion (Fig. 5, ref. 69) configured to at least partly encircle a first one of the pair of non-parallel, elongate members; and a second hook (Fig. 5 below) including a first end (Fig. 5 below) unitary with the shaft at a position axially displaced from the first hook (Fig. 5), said second hook terminating at a second end (Fig. 5 below) spaced laterally from the shaft and comprising a second internal surface (Fig. 5 below) having a curved portion (Fig. 5, ref. 23). The first end, the second end of the second hook, and the shaft define a first plane and the first hook extends laterally from the shaft along the first plane. Since the first hook is not permanently attached to the shaft, it can be angled with respect to the second hook. The shaft has a round or oval cross-sectional profile. Near ref. 61 in Fig. 5, the shaft has a round cross-sectional profile. The shaft defines a substantially planar plate (Fig. 1, ref. 10). The shaft is curved (Fig. 1., ref 33). The apparatus further

comprises a first threaded aperture (Fig. 5, ref. 73) through said shaft and said curved portion of the first hook. The first hook is secured to the first spinal rod and the second hook is secured to a second spinal rod, wherein the first spinal rod and the second spinal rod are positioned to lie non-parallel to each other (Fig. 24). The first spinal rod and the second spinal rod are positioned to not lie in the same plane (Fig. 25).

The apparatus further comprises a threaded aperture (Fig. 4, ref. 27) (column 5, lines 18-20) through said shaft; and a threaded fastener (Fig. 5, ref. 22) (column 5, lines 18-22) threadedly received within said aperture, wherein said aperture and said fastener are positioned to secure an elongate member within the second hook (column 5, lines 22-27).

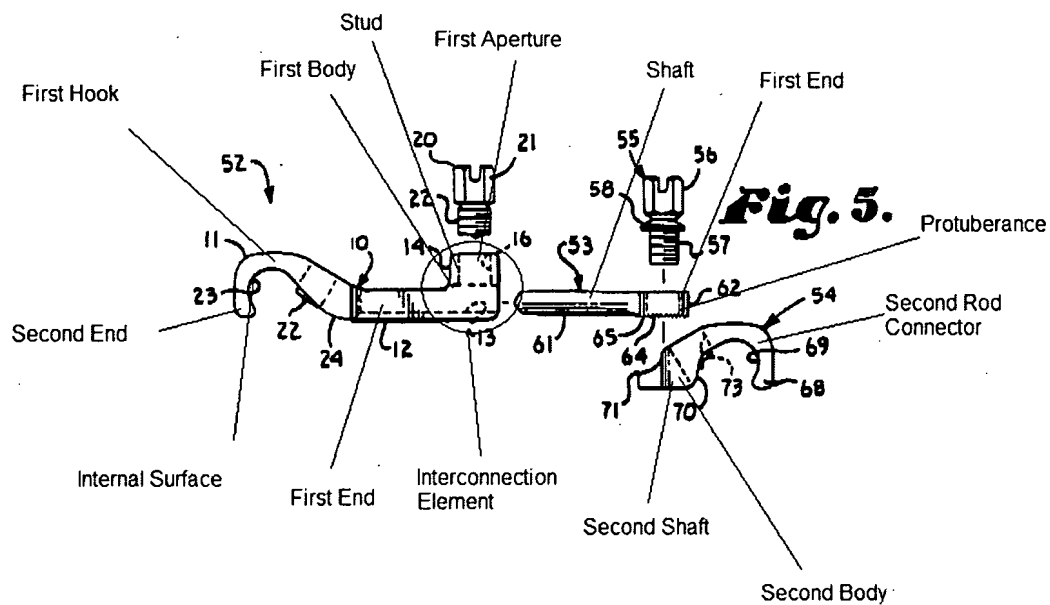
Jackson further discloses an interconnection apparatus for securing a pair of elongate members, said apparatus comprising: a solid shaft (Fig. 5 below); a first hook (Fig. 5 below) including a first internal surface (Fig. 5 below) having a curved portion (Fig. 5, ref. 69) configured to at least partly encircle a first one of the pair of non-parallel, elongate members; and a second hook (Fig. 5 below) including a first end (Fig. 5 below) unitary with the shaft at a position axially displaced from the first hook (Fig. 5), said second hook terminating at a second end (Fig. 5 below) spaced laterally from the shaft and comprising a second internal surface (Fig. 5 below) wherein the second internal surface curves in a first direction from the shaft to the second end (Fig. 5, ref. 23). The apparatus further comprises a first spinal rod (Fig. 2, ref. 3) secured to the first rod connector and a second spinal rod (Fig. 2, ref. 2) secured to the second rod connector, wherein the first spinal rod and the second spinal rod are positioned to lie non-parallel to

each other (Fig. 24). The first spinal rod and the second spinal rod are positioned to not lie in the same plane (Fig. 25).



Jackson further discloses an interconnection apparatus for securing an elongate member, said apparatus comprising: a shaft (Fig. 5 below); a first hook (Fig. 5 below) including a first end connected to the shaft (Fig. 5 below) and terminating at a second end (Fig. 5, below) spaced laterally from the shaft, and an internal surface (Fig. 5) configured to engage the elongate member wherein the internal surface continuously curves in a first direction from the shaft to the second end (Fig. 5, ref. 69). The apparatus further comprises an interconnection element (Fig. 5 below) including a first body (Fig. 5 below) having a first aperture (Fig. 5 below) formed therein and a stud (Fig. 5 below) extending from the body and wherein the shaft is received within the first aperture. The apparatus further comprises a second rod connector (Fig. 5 below) including a second shaft (Fig. 5 below) having a second body (Fig. 5 below) carried

thereon, said second body having a second aperture (Fig. 7, the opening that end 62 is resting in) formed therein, said second aperture being capable of having the stud received therein; and a fastener (Fig. 5, ref. 21) configured to engage with the stud. The apparatus further comprises a first spinal rod secured to the first rod connector and a second spinal rod secured to the second rod connector, wherein the first spinal rod and the second spinal rod are positioned to lie non-parallel to each other (Fig. 24). The first spinal rod and the second spinal rod are positioned to not lie in the same plane (Fig. 25). The shaft terminates in a first end having a protuberance extending laterally therefrom (Fig. 5 below).



The apparatus of Jackson is capable of performing a method of treating a spinal deformity, said method comprising; securing a first spinal rod and a second spinal rod to

two or more vertebrae; interconnecting the first spinal rod and the second spinal rod by securing the first spinal rod to the first hook and the second spinal rod to the second hook (column 4, lines 24-39).

Jackson discloses an interconnection apparatus for securing an elongate member said apparatus comprising: a shaft (Fig. 13, ref. 110), a first hook (Fig. 13, ref. 54) including a first end (Fig. 13, end near ref. 73) connected to the shaft (Fig. 13) and terminating at a second end (Fig. 13, end near ref. 68) spaced laterally from the shaft (Fig. 13) and an internal surface (Fig. 13, ref. 69) configured to engage the elongate member (Fig. 13, ref. 2) wherein the internal surface curves in a first direction from the shaft to the second end (Fig. 13). The apparatus further comprises an interconnection element (Figs. 13 and 14, ref. 103) including a first body (Fig. 14, ref. 136) having a first aperture (Fig. 14, ref. 138) formed therein and a stud (Fig. 14, ref. 135) extending from the body and wherein the shaft is received within the first aperture (Figs. 13 and 14, ref. 110 going into ref. 138). The first hook and the second hook are moveable with respect to the interconnection member, since the components can be disconnected (Fig. 14) and they can be moved with respect to each other. The stud is externally threaded (Fig. 14) (column 8, lines 5-8).

Jackson does not disclose the first and/or second hooks having a ridge or an internal surface having a second curve which curves continuously in a second direction oblique to the first direction.

Assaker discloses first and/or second hooks (Fig. 10, ref 17) (column 5, lines 26-29) having a ridge (Fig. 10, ref. 21) or an internal surface having a second continuous

curve (Fig. 10, ref. 21) used for improved grasping of the vertebral lamina (column 5, lines 18-22). The internal surface curves in a second direction substantially orthogonal to the first direction. The internal surface curves in a second direction at an acute angle to the first direction. The internal surface curves in a second direction at an obtuse angle to the first direction. One can trace curves over the ridge (Fig. 10, ref. 21) that can be considered to be orthogonal to the first direction, acute to the first direction and obtuse to the first direction.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the interconnection apparatus of Jackson with the first and/or second hooks having a ridge or an internal surface having a second curve of Assaker, in order to allow the interconnection apparatus to not only grasp rods, but to also appropriately grasp a vertebra (Assaker, column 5, lines 18-22).

Regarding claims 10, 19, 20 and 27, Jackson in view of Assaker discloses the claimed invention except for the various components being formed as a one-piece unit. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed the device as a one piece unit, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Assaker (US Pat. 5,620,444).

Regarding claims 19 and 20, Assaker discloses the claimed invention except for the various components being formed as a one-piece unit. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have formed the device as a one piece unit, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 13 and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/695,067 in view of Assaker (US Pat. 5,620,444).

Claim 1 of Application No. 10/695,067 discloses the claimed invention except for the internal surface with curves both in a first direction from the shaft to the second end and in a direction oblique to the first direction.

Assaker discloses an internal surface with curves both in a first direction from the shaft to the second end and in a direction oblique to the first direction (Fig. 10, ref. 21) (column 5, lines 18-22), used for improved grasping of the vertebral lamina (column 5, lines 18-22).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the interconnection apparatus of claim 1 of Application No. 10/695,067 with the internal surface with curves both in a first direction from the shaft to the second end and in a direction oblique to the first direction, in order to allow the interconnection apparatus to not only grasp rods, but to also appropriately grasp a vertebra (Assaker, column 5, lines 18-22).

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

With regard to Applicant's argument that the shaft is not solid, the Examiner respectfully disagrees. Upon further consideration the Examiner agrees that the passage previously cited was directed towards a different shaft than the one referred to in the previous Office Action, and as such the grounds of the previous rejection with regard to the cited passage (column 6, lines 23-24) are withdrawn. However, the shaft 25 is solid because it is a solid object (e.g. neither a liquid nor a gas). Solid objects may

be hollow or they may be filled, but solid does not necessarily imply that an object does not have a hollow interior.

Applicant's arguments filed 05/02/2007 directed towards the remaining claims have been fully considered but they are not persuasive.

With regard to Applicant's argument that the internal surface does not curve continuously both in a first direction from the shaft to the second end and in a direction oblique to the first direction, the Examiner respectfully disagrees. The first curve is continuous since it is constantly curving as it forms the hook of the device. The second curve is also constantly curving in a direction oblique to the first direction, as can be seen by the curving line directly below the portion that the line for ref. 21 is touching.

With regard to Applicant's arguments that the device of Assaker and Jackson cannot be combined because the hooks of Jackson cannot be placed on vertebra because of the device's profile, the Examiner respectfully disagrees. While the profiles may differ, the hooks of Jackson are still capable of being used to grasp vertebrae. Vertebrae are complex bony structures that present a variety of different structural features which can accommodate the structure of Jackson (e.g. the spinous processes and the gaps between them).

With regard to Applicant's argument that the references cannot be combined since the surfaces taught by Assaker would interfere with the locking mechanism of Jackson, the Examiner respectfully disagrees. The locking mechanism could still lock a rod in place.

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Regarding the Applicant's argument that Jackson teaches away from a combination with Assaker, the Examiner respectfully disagrees. The deformation referred to in Assaker is directed towards the shafts and connectors of the system, not the curves taught by Assaker. The use of deformation of the shafts and connectors of Assaker does not teach away from the use of the curves of Assaker with the device of Jackson.

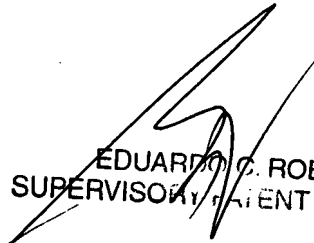
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER